Accompanying Documents

1. Marked-up copies of the originally presented claims incorporating the amendments made herein (Appendix A).
2. Clean copies of the pending claims after incorporation of the amendments made herein (Appendix B).

AMENDMENT

In the Claims:

Please amend claims 15 and 16 as follows.

15. (Twice Amended) A vaccine comprising an immunogenic composition of any one of claims 1-7.

16. (Twice Amended) A method of vaccinating an individual comprising administering to said individual an immunogenic composition of any one of claims 8-14.

REMARKS

Introductory Comments

Claims 1-16 are pending. The Examiner has rejected all pending claims.

The Examiner has rejected claims 1 and 15 under 35 U.S.C. §112, first paragraph, alleging that the specification does not reasonably provide enablement for making a vaccine.

The Examiner has rejected claims 1-16 under 35 U.S.C. §102(b), alleging that the claims are anticipated by U.S. Patent Nos. 4,673,574 to Anderson, and 5,153,312 to Porro *et al.*

These rejections are traversed and believed to be overcome for reasons discussed below.

Applicants acknowledge with appreciation the entry of the Preliminary Amendment and the granting of the priority.

Overview of the Amendments

Claim 15 has been amended to depend from any one of claims 1-7. The amendment finds support in the claims as originally presented.

Claim 16 has been amended to depend from any one of claims 8-14. The amendment finds support in the claims as originally presented.

No new matter has been added by way of these amendments.

Addressing the Examiner's Objections and Rejections

1. Rejection of Claims 1 and 15 under 35 U.S.C. §112, First Paragraph

The Examiner has rejected claims 1 and 15 under 35 U.S.C. §112, first paragraph, asserting that the specification does not reasonably provide enablement for making a "vaccine." The Examiner cites R.W. Ellis as supporting the proposition that using a single antigen for vaccination is unpredictable, and states that since working examples for vaccination were not included in the specification, the claims relating to vaccination are too broad.

Applicants traverse the rejection. The test for enablement is "whether one skilled in the art could make or use the claimed invention from the disclosure in the patent coupled with information known in the art without undue experimentation." United States v Telectronics, Inc. 8 USPQ2d 1217 (Fed. Cir. 1988); In re Wands, 8 USPQ2d 1400 (Fed Cir. 1988). Thus, in order to satisfy Section 112 regarding enablement, the specification need only set forth such information as is sufficient to allow one of ordinary skill in the art to make and use the invention. How such a teaching is accomplished, either by the use of illustrative examples or by broad terminology, is of no importance since a specification which teaches how to make and use the invention in terms which correspond in scope to the claims must be taken as complying with the first paragraph of §112 unless there is reason to doubt the objective truth of the statements relied upon therein for enabling support (*In re Marzocchi*, 169 USPQ 367 (CCPA 1971)). The burden is on the Office to explain its reasons for the rejection and support the rejection with (i) acceptable evidence, or (ii) reasoning which contradicts the applicants' claim: the reasoning must be supported by current literature as a whole and the Office

must prove the disclosure requires undue experimentation. *In re Marzocchi*, 439 F.2d 220, 223-24, 169 USPQ 367, 369-70 (CCPA 1971).

The immunogenic composition of claim 1 comprises a NmC oligosaccharide conjugated to a first carrier and NmB outer membrane protein. The Examiner acknowledges that the specification is enabling for making an immunogenic composition. Since claim 1 recites an immunogenic composition, and does not have "vaccine" as an element, it should not have been rejected.

Claim 15 recites a vaccine comprising an immunogenic composition of claim 1. The specification at page 3 lines 21-23, defines the term "vaccine" to mean an immunogenic composition which is able to induce a microbicidal immune response. Examples 1 and 2 provide detailed methods for measuring the immunogenic response to the composition of the invention. The results are summarized in Tables 2 and 3 and shown in Figures 1A, 1B, 2A, and 2B. The results clearly show that the combination elicited high titers of bactericial antibody for both NmB and NmC. The applicants have thus taught one of skill in the art how to make and use the immunogenic composition of claim 1 and the vaccine of claim 15. The Office has failed to provide adequate evidence to support the present rejection. Without such evidence, a rejection under 35 U.S.C. §112, first paragraph for lack of enablement cannot be sustained. The Examiner is respectfully requested to withdraw this rejection. Should the Office choose to continue to reject the claims under 35 U.S.C. §112, first paragraph for lack of enablement, the applicants request, pursuant to 37 C.F.R. §1.104(d)(2), that the Office support the rejection with specific data and a supporting affidavit to prove that the disclosure requires undue experimentation.

2. The Rejection of Claims 1-16 Under 35 U.S.C. §102(b)

The Examiner has rejected claims 1-16 under 35 U.S.C. §102(b), asserting that the claims are anticipated by USPN 4,673;574 to Anderson and USPN 5,153,312 to Porro *et al.* The Examiner stated that Anderson disclosed an immunogenic composition comprising an oligosaccharide conjugated to a carrier and an outer membrane protein, wherein the carrier is CRM_{197}. The Examiner characterized Porro *et al.* as disclosing a method of making an immunogenic composition comprising an oligosaccharide

conjugated to a carrier and an outer membrane protein, further where the composition may be used in vaccine preparations.

To anticipate a claim, a single source must contain all of the elements of the claim. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379, 231 USPQ 81, 90 (Fed. Cir. 1986). *Atlas Powder Co. v. E. I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1574, 224 USPQ 409, 411 (Fed. Cir. 1984). Moreover, the single source must disclose all of the claimed elements "arranged as in the claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 9 USPQ 2d 1913, 1920 (Fed. Cir. 1989); *Connell v. Sears Roebuck & Co.*, 722 F.2d 1542, 1548, 220 USPQ 193, 198 (Fed. Cir. 1983). Finally, the law requires identity between the claimed invention and the prior art disclosure. *Kalman v. Kimberly-Clar Corp.* 713 F.2d 760, 771, 218 USPQ 2d 781, 789 (Fed. Cir. 1983, cert. denied, 465 U.S. 1026 (1984)).

The present invention relates to a composition that induces an immune response to two serogroups of *Neisseria meningitidis*. The immunogenic composition comprises an NmC (*Neisseria meningitidis* C) oligosaccharide conjugated to a first carrier and NmB (*Neisseria meningitidis* B) outer membrane protein. The present invention thus relates to combination immunogenic compositions and vaccines for *Neisseria meningitidis* B and C. The combinations are mixed, in that the immunogenic response is elicited against an oligosaccharide and a protein.

In contrast, both Anderson and Porro *et al.* teach compositions of oligosaccharides only. Neither Anderson nor Porro *et al.* teach or disclose immunogenic compositions comprising mixed components where one antigen is an oligosaccharide and the other antigen, from a different organism, is a protein. In fact, both cited references pertain to vaccines for pneumococcal infection consisting of capsular polysaccharides conjugated to a carrier protein, such as a bacterial toxin or toxoid, whereas the applicants invention pertains to vaccines to *Neisseria meningitidis* B and C. Anderson discloses the preparation of immunogenic conjugates by first oxidatively hydrolyzing capsular polysaccharides to obtain a fragment, and then conjugating the fragment to a bacterial toxin. Anderson does not teach or suggest an immunogenic composition comprising an NmC oligosaccharide conjugated to a first carrier and NmB outer membrane protein. In fact, at column 1, lines 48-49, Anderson states that amino acid-containing polymers are

excluded from their invention. In the present invention, NmB outer membrane protein is an element of the claim, while Anderson explicitly affirms that proteins are not included in their compositions.

The other reference, Porro *et al.*, discloses an improved synthetic method for conjugating an oligosaccharide with a carrier protein using reductive amination. It also does not teach or disclose the use of NmB outer membrane protein in an immunologic composition.

Neither of the cited references contain all the elements of claims 1-16, and one of the references explicitly excludes an element of applicants' invention. Therefore, the cited references do not anticipate the claims, and the Examiner is respectfully requested to withdraw this rejection.

CONCLUSION

Applicants respectfully submit that the claims comply with the requirements of 35 U.S.C. §112 and define an invention that is patentable over the art. Accordingly, a Notice of Allowance is believed in order and is respectfully requested.

Please send all further written communications in this case to:

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Respectfully submitted,

Date: November 27/2001

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APPENDIX A

Marked up Version of The Claims.

15. (Twice Amended) A vaccine comprising an immunogenic composition of [claim 1] <u>any one of claims 1-7</u>.

16. (Twice Amended) A method of vaccinating an individual comprising administering to said individual an immunogenic composition of [claim 1] <u>any one of claims 8-14</u>.